Reference number(s)
1905-A

# SPECIALTY GUIDELINE MANAGEMENT

## HERCEPTIN (trastuzumab)
## OGIVRI (trastuzumab-dkst)
## KANJINTI (trastuzumab-anns)
## TRAZIMERA (trastuzumab-qyyp)

**POLICY**

### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications[1-4]
   1. Adjuvant breast cancer
      Treatment of human epidermal growth factor receptor 2 (HER2)-overexpressing node positive or node negative (estrogen receptor (ER)/progesterone receptor (PR) negative or with one high risk feature) breast cancer:
      a. As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
      b. As part of a treatment regimen with docetaxel and carboplatin
      c. As a single agent following multi-modality anthracycline based therapy
   2. Metastatic breast cancer
      a. In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer
      b. As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease
   3. Metastatic gastric cancer
      In combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma, who have not received prior treatment for metastatic disease

B. Compendial Uses[5-7]
   1. HER2-positive breast cancer
      a. Neoadjuvant therapy
      b. Treatment of recurrent or stage IV (M1) disease
   2. Intra-cerebrospinal fluid (CSF) treatment for leptomeningeal metastases from breast cancer
   3. HER2- positive esophageal and esophagogastric junction cancer
   4. HER2- positive advanced and recurrent uterine serous carcinoma
   5. HER2- positive salivary gland tumor

All other indications are considered experimental/investigational and not medically necessary.

### II. DOCUMENTATION

Submission of human epidermal growth factor receptor 2 (HER2) status is necessary to initiate the prior authorization review, where applicable.

## III. CRITERIA FOR INITIAL APPROVAL

### A. Breast Cancer[1-6]

1. Authorization of up to 12 months may be granted for neoadjuvant treatment of HER2-positive breast cancer as part of a complete treatment regimen.
2. Authorization of up to 12 months may be granted for adjuvant treatment of HER2-positive breast cancer.
3. Authorization of 12 months may be granted for treatment of HER2-positive recurrent or metastatic breast cancer.
4. Authorization of 12 months may be granted for intra-CSF treatment for leptomeningeal metastases from breast cancer.

### B. Esophageal, Gastric, or Gastroesophageal Junction Cancer[1-5,7]

Authorization of 12 months may be granted for treatment of HER2-positive esophageal, gastric, or gastroesophageal junction cancer in combination with chemotherapy.

### C. Uterine Serous Carcinoma[5]

Authorization of 12 months may be granted for treatment of HER2-positive advanced and recurrent uterine serous carcinoma in combination with carboplatin and paclitaxel.

### D. Salivary Gland Tumor[5]

Authorization of 12 months may be granted for treatment of recurrent HER2-positive salivary gland tumors with distant metastases.

## IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continuation of therapy for an indication outlined in section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. Adjuvant and neoadjuvant treatment of breast cancer will be approved for a total of 12 months of therapy.

## V. REFERENCES

1. Herceptin [package insert]. South San Francisco, CA: Genentech, Inc.; November 2018.
2. Kanjinti [package insert]. Thousand Oaks, CA: Amgen, Inc.; June 2019.
3. Ogivri [package insert]. Zurich, Switzerland: Mylan GmbH; December 2017.
4. Trazimera [package insert]. Cork, Ireland: Pfizer; November 2019.
5. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed August 13, 2019.
6. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 3.2018. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed August 13, 2019.
7. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers. Version 2.2018. https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf. Accessed August 13, 2019.

DOCUMENT HISTORY

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|---|---|
| Created: | Specialty Clinical Development (GY) 06/2010 |
| Revised: | GY 10/2010 (new boxed warning), KH 08/2011, LD 08/2012, 02/2013 (added Kadcyla), KW 08/2013, JP 08/2014, TS 07/2015 HY 08/2016, ST 01/2017 (annual, separated from Herceptin-Kadcyla SGM), TE 01/2018 (annual and added Ogivri), BI 01/2019, LP 08/2019a (added Kanjinti) LP 08/2019b (alignment), ST 03/2020 (added Trazimera) |
| Reviewed: | CDPR / KP 08/2010, 10/2010, KP 09/2011, KP 08/2012, DNC 03/2013, DNC 08/2013, 08/2014, LCB 08/2015, DNC 08/2016, AN 02/2017, ME 01/2018, AN 02/2018, EPA 02/2019, CHART 08/29/2019, 03/26/2020 |

External Review: 10/2010, 11/2011, 10/2012, 03/2013, 10/2013, 09/2014, 09/2015, 09/2016, 03/2017, 03/2018, 03/2019, 10/2019